RECORD AND BRIEFS

Supreme Court, U.S.
FILED
OCT 30 2017
OFFICE OF THE CLERK

No. 16-712

IN THE
Supreme Court of the United States

OIL STATES ENERGY SERVICES, LLC.,
Petitioner,

v.

GREENE'S ENERGY GROUP, LLC, ET AL.,
Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR AARP AND AARP FOUNDATION AS AMICI CURIAE IN SUPPORT OF RESPONDENTS

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INTEREST OF AMICI CURIAE[1]

AARP is the nation's largest nonprofit, nonpartisan organization dedicated to empowering Americans 50 and older to choose how they live as they age. With nearly 38 million members and offices in every state, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands, AARP works to strengthen communities and advocate for what matters most to families, with a focus on health security, financial stability, and personal fulfillment. AARP's charitable affiliate, AARP Foundation, works to ensure that low-income older adults have nutritious food, affordable housing, a steady income, and strong and sustaining bonds.

AARP and AARP Foundation have a longstanding interest in individuals' access to affordable healthcare, including access to lower-cost prescription drugs. In light of the impact that the cost of drugs in particular has on healthcare expenditures, AARP's Public Policy Institute (PPI) has been tracking the cost of widely used prescription drugs since 2004 and publishes the Rx Price Watch series, reporting on changes in the cost of drugs widely used by older Americans.[2] In a report dated December 2016, PPI determined that brand name prescription drug prices

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[1] In accordance with Supreme Court Rule 37.6, AARP and AARP Foundation state that: (1) no counsel to a party authored this brief, in whole or in part; and (2) no person or entity, other than AARP Foundation, AARP, its members and its counsel have made a monetary contribution to the preparation or submission of this brief. The parties have consented to the filing of amicus briefs through the filing of blanket consent letters.

[2] The latest reports on trends in the retail prices of generic, brand-name, and specialty drugs are available at http://www.aarp.org/ppi/info-2016/trends-in-retail-prices-of-drugs.html.

increased for the fourth straight year by double digits.[3] Other data collected suggest that almost 20% of those taking prescription drugs have skipped a drug or cut the dose to reduce the cost.[4] AARP and AARP Foundation have filed several amici curiae briefs before this Court in cases that impact the cost of healthcare. *E.g., Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013); *Fed. Trade Comm'n v. Actavis*, 133 S. Ct. 2223 (2013). AARP and AARP Foundation briefs also have supported the use of inter partes review (IPR) to expedite the removal of invalid patents and thus enable faster drug entry for the benefit of consumers and the U.S. healthcare system. *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131 (2016).

Inasmuch as invalid patents have a direct impact on the cost of healthcare, to the detriment of older individuals and the general public, AARP and AARP Foundation submit this brief urging the Court to affirm the decision below.

SUMMARY OF THE ARGUMENT

Congress passed the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (2011), to improve patent quality and address a growing concern that patent litigation was negatively affecting the climate for investment and innovation. The AIA created IPR, a time-limited review

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[3] Stephen W. Shondelmeyer & Leigh Purvis, *AARP: Rx Price Watch Brand Name Prescription Drug Prices Increase by Double-Digit Percentage for Fourth Straight Year* (Dec. 2016), http://www.aarp.org/content/dam/aarp/ppi/2016-12/brand-name-prescription-drug-prices-increase.pdf.

[4] Robert Love, *Why our Drugs Cost So Much*, AARP Bulletin (May 2017), *http://www.aarp.org/health/drugs-supplements/info-2017/rx-prescription-drug-pricing.html*.

process, that allows the Patent Trial and Appeal Board (PTAB) to review the patentability of one or more claims in a patent only on the limited grounds of 35 U.S.C. §§ 102 or 103. *See* 35 U.S.C. § 311(b). The IPR process is designed to correct the issuance of invalid patents. The process provides no right to monetary damages; it affords only the relief of cancellation of a patent.

When patents are invalid, they undermine competition and increase healthcare and other consumer costs, with no offsetting benefit to consumers. The cost of litigating patent claims that result from poor patent quality is exceedingly high to both businesses and consumers. *See* Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part II of II*, 21 Fed. Circuit B.J. 539, 600 (2012). The intent of the AIA was to create a streamlined process to correct the errors of the Patent and Trademark Office (PTO) and allow "invalid patents that were mistakenly issued by the PTO to be fixed early in their life, before they disrupt an entire industry or result in expensive litigation." 157 Cong. Rec. S1323, 1326 (daily ed. Mar. 7, 2011) (statement of Sen. Sessions).

As a result of the monopolies created by drug patents, healthcare consumers pay ever-increasing prices for prescription medications. The public has a paramount interest in seeing that patent monopolies are kept within their legitimate scope. Invalid patents can have a direct impact on the cost of pharmaceutical drugs to the public, generally, and particularly to the detriment of older individuals, who disproportionately rely upon pharmaceuticals for their health. Medical device costs also may be artificially inflated when invalid patents are issued. The PTAB should be permitted to correct the PTO's errors (including errors in not finding

relevant prior art), and third parties should be able to ask them to do so without spending millions of dollars in traditional district court litigation. The Court should affirm the judgment of the Federal Circuit.

ARGUMENT

I. Congress Passed the AIA to Address a Growing Concern That Patent Litigation Was Negatively Affecting the Climate for Investment and Innovation.

Congress passed the AIA to "improve patent quality" and address a growing concern that the costs of patent litigation were negatively affecting the climate for investment and innovation. H.R. Rep. No. 98-112, pt. 1, at 39-40, 48 (2011). The cost of litigating patent claims that result from poor patent quality was noted to be exceedingly high to both businesses and consumers. *See* Matal, *supra*, at 600 (noting that the cost of litigating against a dubious patent can be millions of dollars and that "it is often prohibitively expensive or even impossible to test the validity of a newly-issued patent that is of dubious validity, and that the continued existence of a patent can disrupt product development in a field of technology for years.")

Congress created the IPR process to "establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs," in response to "a growing sense that questionable patents are too easily obtained and are too difficult to challenge." H.R. Rep. No. 98-112, pt. 1, at 39-40. Essentially, the AIA was designed to get rid of patents that should not have been issued in the first place. One of the

purposes of the act was "to correct egregious errors" made by the PTO in granting patents. *See* 157 Cong. Rec. S7413-14 (daily ed. Nov. 14, 2011) (statement of Sen. Kyl).

In discussing the bill that became the AIA, Senator Amy Klobuchar observed that the PTO "too often issues low-quality patents" and noted that:

> The legislation also provides a modernized streamlined mechanism for third parties who want to challenge recently issued, low-quality patents that should never have issued in the first place. Eliminating these potentially trivial patents will help the entire patent system by improving certainty for both users and inventors.

157 Cong. Rec. S1034,1036-37 (daily ed. Mar. 1, 2011) (statement of Sen. Klobuchar); *see also* 157 Cong. Rec. S1323,1326 (daily ed. Mar. 7, 2011) (statement of Sen. Sessions) ("This will allow invalid patents that were mistakenly issued by the PTO to be fixed early in their life, before they disrupt an entire industry or result in expensive litigation"); 157 Cong. Rec. S5370, 5374 (daily ed. Sep. 7, 2011) (statement of Sen. Whitehouse) ("Unfortunately, numerous poor quality patents have issued in recent years, resulting in seemingly endless litigation that casts a cloud over patent ownership").

It is well known that the PTO receives a large number of patent applications. In 2016, applicants filed over 650,000 new patent applications requiring examination. USPTO Perf. and Accountability Rep. FY 2016, at 78. The PTO's initial determinations granting patents are often reached "under

tight time constraints and on an *ex parte* basis allowing minimal opportunity to hear a third party's opposing views." Fed. Trade Comm., *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* 28 (Oct. 2003), http://1.usa.gov/1d7fQwQ. Given the fact that patents are granted on an *ex parte* basis, without the benefit of the views of other interested parties, several commentators have noted that it is not surprising that mistakes in granting patents are made. *E.g.*, Doug Lichtman & Mark Lemley, *Rethinking Patent Law's Presumption of Validity*, 60 Stan. L. Rev. 45, 47 (2007) (noting that, given the high volume of patent applications, "it is hardly a surprise that the PTO makes mistakes during the initial process of patent review, granting patents that, on the merits, should never have been issued"). The IPR process is designed to correct these mistakes. The process provides no right to monetary damages; it affords only the relief of cancellation of a patent.

II. Prolonged Patent Litigation Can Inhibit Medical Research.

Prolonged patent litigation and the omnipresent threat of multi-million dollar patent lawsuits are known to have a chilling effect on medical research. As an example, prior to the decision in *Association for Molecular Pathology v. Myriad Genetics*, *supra*, there were a number of patent infringement lawsuits that "cast a pall over the Alzheimer's-research field." Erica Check Hayden, *Patent Dispute Threatens US Alzheimer's Research*, 472 Nature 20 (2011), http://www.nature.com/news/2011/110405/full/472020a.html. For example, the Alzheimer's Institute of America, Inc., sued several defendants who were in the course of Alzheimer's Disease research. *See, e.g, Alzheimer's Inst. of Am., Inc. v. Avid RadioPharmaceuticals*, No. 2:10-cv-06908-TJS, 2015 U.S.

Dist. LEXIS 40013 (E.D. Pa. Mar. 30, 2015); *Alzheimer's Inst. of Am., Inc. v. CoMentis, Inc.*, No. 5:09-cv-01366-F, 2012 U.S. Dist. LEXIS 197821 (W.D. Okla. Dec. 17, 2012); *Alzheimer's Inst. of Am., Inc. v. Elan Pharmaceuticals, Inc.*, No. 3:10-cv-00482-EDL, 2012 U.S. Dist. LEXIS 196376 (C.D. Cal. Aug. 3, 2012); *Alzheimer's Inst. of Am., Inc. v. Pfizer, Inc.*, No. 4:09-cv-01026-CAS (E.D. Mo. dismissed Nov. 12, 2010). Elan Pharmaceuticals, Inc., which owns Athena Neurosciences, Inc., also filed a lawsuit against the Mayo Foundation, alleging that Mayo's use and distribution of transgenic mice infringed patents held by Elan. *Elan Pharmaceuticals v. Mayo Found. for Med. Educ. & Research*, 346 F.3d 1051 (Fed. Cir. 2003).

The cost of eliminating invalid patents in these lawsuits can be devastating to the defendants—particularly for universities and other non-profit institutions. In the *Avid RadioPharmaceuticals* case above, Avid spent over $6.5 million in attorneys' fees and $222,000 in costs trying a patent case that resulted in a defense verdict. Declaration of L. Scott Burwell in Support of Avid RadioPharmaceuticals' Motion for Attorney's Fees under 35 U.S.C. § 285, *Avid*, No. 2:10-cv-06908-TJS (E.D. Pa. June 1, 2012), ECF No. 317-4; Avid RadioPharmaceuticals' Bill of Costs and Incorporated Supporting Memorandum, *Avid*, No. 2:10-cv-06908-TJS (E.D. Pa. June 1, 2012), ECF No. 318-1. Additionally, as one Alzheimer's researcher noted, lawsuits over patents "constitute a large drain on valuable scientific resources at a time when scientific funds are increasingly tight." Hayden, *supra*, at 20 (quoting Benjamin Wolozin, an Alzheimer's researcher at Boston University).

III. Invalid Patents Foreclose Competition and Increase Consumer Costs.

This Court recently reaffirmed the important patent policy of eliminating unwarranted patent grants so that the public will not "continually be required to pay tribute to would-monopolists without need or justification." *Actavis*, 133 S. Ct. at 2233 (quoting *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969)). When patents are improperly granted, competition in the marketplace is foreclosed and the public is forced to pay higher prices. *McNeil-PPC, Inc. v. L. Perrigo Co.*, 337 F.3d 1362, 1368 (Fed. Cir. 2003). This Court has often recognized that "[i]t is the public interest which is dominant in the patent system." *Edward Katzinger Co. v. Chicago Metallic Mfg. Co.*, 329 U.S. 394, 401 (1947) (quoting *Mercoid Corp. v. Mid-continent Investment Co.*, 320 U.S. 661, 665 (1944)) (internal quotation marks omitted). It is as "important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly." *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892). "Large numbers of improvidently granted patents may create *in terrorem* effects on entrepreneurship, ranging from holdup licensing to patent thickets." John R. Thomas, *The Responsibility of the Rulemaker: Comparative Approaches to Patent Administration Reform*, 17 Berkeley Tech. L.J. 727, 731 (2002).

Unfortunately, the costs of patent litigation "are inevitably passed onto consumers, regardless of the outcome of the case." Brianna Lennon, *Antitrust Implications of Technology Patents*, 1 ABA Young Lawyer Div. Antitrust Law Comm. Newsl. 8, 9 (2012), http://bit.ly/1fej47A; Megan M. La Belle, *Standing to Sue in the Myriad Genetics Case*, 2 Calif. L.

Rev. Circuit 68, 85 (2011) ("[W]hen private parties invalidate bad patents the public as a whole benefits from robust competition, increased consumer choice, and lower prices. . . . While patent litigation certainly implicates private interests, the public is the primary intended beneficiary of our patent system.")

Improperly granted patents also increase the cost of health care to the detriment of older people and the public, generally. Health care costs are a growing burden for middle-class families across all age groups. A significant number (one in five) have problems paying medical bills. Many of these families experience serious financial stress, such as problems paying for other necessities such as food, clothing, and housing, or medically related bankruptcy.[5]

IV. The IPR Process Provides Distinct Advantages Over Litigating Invalid Patents.

A. The IPR Process Complements the Hatch-Waxman Act's Statutory Scheme.

Drug manufacturers that intend to market a generic version of a patented brand-name drug product may pursue expedited Food and Drug Administration (FDA) approval by filing an Abbreviated New Drug Application (ANDA)

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[5] Harriet Komisar, *The Effects of Rising Health Care Costs on Middle-Class Economic Security, Middle Class Security Project, An Initiative of the AARP Public Policy Institute* 1, 6 (Jan. 2013), http://www.aarp.org/content/dam/aarp/research/public_policy_institute/security/2013/impact-of-rising-health care-costs-AARP-ppi-sec.pdf.

pursuant to the Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). *See* 21 U.S.C. §355(j) (describing ANDA procedures). In response to a common form of ANDA filing known as Paragraph IV certification, where the generic certifies that the patent either does not apply to it, or is invalid, patented brand-name drug makers may bring patent infringement suits against the ANDA applicant under the Hatch-Waxman Act. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (allowing Paragraph IV certification, whereby a generic manufacturer certifies that the brand-name product's underlying patents are invalid or will not be infringed); 35 U.S.C. § 271(e)(2)(A) (authorizing suit following Paragraph IV certification). When such suits are brought, the FDA is statutorily prohibited from approving the applicant's ANDA for thirty months unless the district court decides the patent is invalid or not infringed before the expiration of this thirty-month stay. 21 U.S.C. § 355(j)(5)(B)(iii)(I); *Actavis*, 133 S. Ct. at 2228. As noted by the Generic Pharmaceutical Association, "[b]rand-name drug makers have a strong interest in delaying resolution of such cases to maximize the benefits of the 30-month stay, and thus often sue in slower jurisdictions." Brief of Generic Pharmaceutical Association and America's Health Insurance Plans as Amici Curiae at 2, *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131 (2016). ANDA applicants and the consumers who depend on generic and biosimilar drugs have a correspondingly strong interest in the resolution of patent issues as quickly as possible.

The IPR system for challenging patents created by the AIA is a valuable tool for ANDA applicants. While amici curiae PhRMA and the Biotechnology Industry Organization urged Congress to exempt certain biopharmaceutical patents

on approved medicines from the IPR system,[6] Congress has chosen not to do so. IPRs continue to serve as a valuable tool for ANDA applicants to resolve patent issues regarding obviousness and novelty more quickly than is possible through district court jurisdiction. This furthers the congressionally mandated goal of the Hatch-Waxman Act, which is to "get generic drugs into the hands of patients at reasonable prices – fast." *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991).[7]

B. Generic Companies Use the IPR Process to Cancel Invalid Patents.

An example of a generic IPR challenge concerns an antioxidant compound in the Exelon skin patch found to be useful in the treatment of Alzheimer's Disease. In April 2017, the Federal Circuit affirmed the PTAB's determination that various claims of two patents directed to the Exelon skin patch were invalid as obvious. *Novartis AG v. Noven Pharms, Inc.*,

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[6] *See* Letter from James C. Greenwood, Pres. & CEO of BIO & John C. Castellani, Pres. & CEO of PhRMA to Members of House & Senate Judiciary Comm. (July 15, 2015), *available at* goo.gl/aBV8Nn.

[7] It should be noted that Congress has balanced the public's need for generic medicines to encourage and fairly compensate the pharmaceutical industry. Congress allows the terms of patents on drug products to be extended beyond twenty years to account for delays before the FDA. *See* 35 U.S.C. § 156. In addition, Congress grants years of market exclusivity upon FDA approval, regardless of whether the product is covered by a patent at all. New "small-molecules" (i.e., traditional pharmaceutical drugs), receive at least five years of exclusivity before a generic can be marketed, sometimes over seven years, depending on their indication. *See* 21 U.S.C. § 355(c)(3)(E)(ii)-(iv); 21 U.S.C. § 355(j)(5)(F)(ii)-(v). Biologics, in turn, receive an even longer boost, with twelve years of market exclusivity applied. *See* 42 U.S.C. § 262(k)(7)(A). That market exclusivity is intended to apply to valid patents, not invalid patents granted in error by the PTO.

853 F.3d 1289 (Fed. Cir. 2017) (affirming the results of IPR2014-00549, IPR2014-00550, IPR2015-00265, and IPR2015-00268). Based on Federal Circuit's affirmance of the PTAB's decision, Noven is free to launch its own generic form of the Exelon patch. Prior generic versions sell for as low as $135 for thirty patches compared to over $565 for brand patches, a 76% discount.[8]

Currently, a number of successful IPR decisions involving pharmaceutical drugs are pending review before the United States Court of Appeals for the Federal Circuit. For example, Copaxone, a synthetic protein used to treat relapses in multiple sclerosis, has been approved since 2002; however, multiple patents remain listed for Copaxone that do not expire until 2030 or beyond.[9] In 2014, the exclusive licensee of the Copaxone patents, Teva, filed multiple suits against several companies, including Mylan and Amneal. The litigation included assorted claims of three patents that cover a method of administering the compound at a high dose and all claims of a later issued patent for such use. During litigation, Mylan and Amneal challenged the validity of the patents through IPR proceedings. In 2016, the PTAB issued decisions invalidating claims of three Copaxone patents that cover a method of administering the compound at a high dose.[10] An

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[8] *Compare* GoodRx.com at https://goo.gl/12QsF1, to GoodRx.com at https://goo.gl/KUHPQx.

[9] *See* United States Food and Drug Administration, *Orange Book: Approved Drug Products with Therapeutic Evaluations*, "Patent and Exclusivity for: N020622," https://goo.gl/seNWNp.

[10] *Mylan Pharms, Inc. v. Yeda Research & Development Co.*, Nos. IPR2015-00830 (P.T.A.B. Sept. 1, 2016), IPR2015-00643 (P.T.A.B. Aug. 24, 2016), IPR2015-00644 (P.T.A.B. Aug. 24, 2016); *see also* Shruti Mehta,

IPR on the fourth patent for such use is pending.[11] The only available generic version of Copaxone currently offered is in the less-prescribed lower dose. While the cost of generic and brand drugs can change daily, in October, 2017 the generic version sold for as low as $2,088 per carton compared to $7,263 per carton for the brand, a 71% savings,[12] suggesting that generic competition on the high-dose versions will have a large effect on price.

In addition to Copaxone, the Federal Circuit is reviewing the PTAB's invalidation of various claims covering Durezol,[13] an eye drop used to treat pain, redness, and swelling after eye surgery; Gattex, a treatment for short bowel syndrome;[14] Kerydin, a drug that treats toenail fungus;[15] and the only patent remaining to cover Diprivan, a drug used in

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Copaxone Litigation in the US: Generics soon to be launched? IMS Health (Mar. 2017), https://goo.gl/YQAUwH.

11 See Mehta, *supra* note 10, at 6.

12 *See* GoodRx, *http://www.GoodRx.com* (comparing prices for drugs by retail pharmacy and location), https://www. goodrx.com/copaxone?drug-name=Copaxone (last visited Oct. 10, 2017).

13 *See Senju Pharm. Co., Ltd. v. Akorn, Inc.*, App. No. 17-1511 (Fed. Cir. appeal docketed, Jan. 24, 2017); *Akorn, Inc. v Senju Pharm. Co., Ltd.*, No. IPR2015-01205 (Nov. 22, 2015).

14 *See In re NPS Pharms., Inc.*, App. No. 17-1392 (Fed. Cir. appeal docketed, Dec. 21, 2016); *Coal. For Affordable Drugs II LLC v. NPS Pharm., Inc.*, No. IPR2015-00990 (Oct. 21, 2016).

15 *See Anacor Pharms., Inc. v. Matal*, App. No. 17-1947 (Fed. Cir. appeal docketed, Apr. 25, 2017); *Coal. For Affordable Drugs X LLC v. Anacor Pharms., Inc.*, Nos. IPR2015-01776; IPR2015-01780; IPR2015-1785 (Feb. 23, 2017).

conjunction with anesthesia.[16] While Diprivan is relatively inexpensive (under $50 for most surgeries), the others carry substantial price tags: Durezol costs at least $175 a bottle,[17] Kerydin costs over $625 for a bottle,[18] and Gattex has retail price of $295,000 a year.[19]

C. Biosimilar Companies Use the IPR Process to Cancel Invalid Patents.

The rise of biotechnology in the late 1980s and early 1990s led to new therapies, so-called biologic drugs, which are derived from natural, biological sources. Biologics are quickly emerging as a vital tool in the fight against many chronic and life-threatening conditions that acutely or disproportionately affect older adults, including arthritis and cancer. Steven Kozlowski, et al., *Developing the Nation's Biosimilar Program*, 365 New Eng. J. Med. 385, 386 (Aug. 4, 2011). Unfortunately, the potential of biologics to treat life-threatening conditions comes at a steep cost to consumers, taxpayers, and insurers, as the prices for these drugs far exceed those of traditional prescription drugs, with some companies charging $200,000 a year or more. Francis Megerlin, et al., *Biosimilars and the*

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[16] *See Fresenius Kabi USA, LLC v. Bass*, App. No. 17-2402 (Fed. Cir. appeal docketed, Aug 8, 2017); *J. Kyle Bass et al. v. Fresenius Kabi USA, LLC*, No. IPR2016-00254 (June 7, 2017).

[17] GoodRx, "Durezol," https://www.goodrx.com/durezol?drug-name=durezol (last visited October 10, 2017).

[18] GoodRx, "Kerydin," https://www.goodrx.com/kerydin?drug-name=kerydin&form=bottle-of-topical-solution&dosage=4ml-of-5%25& quantity=1&days_supply=&label_override= Kerydin (last visited October 10, 2017).

[19] Jillian Dabney, *Shire's Acquisition Gives It Natpara and Gattex*, Market Realist (Apr. 7, 2015), https://goo.gl/rMtyQM.

European Experience: Implications for the United States, 32 Health Aff. 1803 (Oct. 2013).

In 2009, Congress passed the Biologics Price Competition and Innovation Act (BPCIA), Pub. L. No. 111-148, 124 Stat. 119 (2009), to create competition for biologics. The BPCIA provides a mechanism for bringing "biosimilar" products to market, establishing an elective process for biosimilar companies and brand companies to negotiate the scope and content of patent infringement actions relating to biologics prior to commercial launch by the biosimilar. [20] Although biosimilar programs in the United States are still in their infancy, biosimilar products also have the potential to mitigate the costs of brand prescriptions. While only a few biosimilar products have been launched in the United States, the products are selling at a discount over biologics. The first biosimilar in the United States approved under the BPCIA, Zarxio, a biosimilar drug used to treat neutropenia in chemotherapy, was launched in September 2015 at a 15% discount to the brand product Neupogen.[21] Two biosimilars to

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[20] *Sandoz Inc. v. Amgen Inc.*, 582 U.S. ___, slip op. at 4-8 (2017).

[21] Ben Hirschler & Michael Shields, *Novartis launches first U.S. 'biosimilar' drug at 15 percent discount*, Reuters (Sept. 3, 2015), https://goo.gl/Y4mUtk. Commentators have noted that Sandoz's launch of Zarxio was an "at risk launch," since Amgen has asserted patent infringement claims. *Sandoz Launches First Biosimilar Drug in U.S.*, Nat'l L. Rev. (Sept. 4, 2015). Zarxio was approved by the FDA over 25 years ago. Amgen brought suit against Sandoz on Zarxio in October 2014; currently the case is on remand to the Federal Circuit after being heard by this Court. *See Amgen Inc. et al. v. Sandoz Inc.*, Case No. 2015-1499 (Fed. Cir.) (on remand).

Remicade, a medication to treat Crohn's Disease, are also available in the United States, with the latest product providing a discount of 35% compared to the brand.[22]

Biosimilar companies are using the IPR process to try to speed the entry of biosimilar products.[23] Biologic products are often covered by a "patent thicket," i.e., a large group of patents that cover more than the biologic compound itself.[24] For example, patents on biologics may include several patents directed to the biotechnology that made the biologic, patents on the cell line that produces the biologic, multiple patents relating to cell culture conditions, and various patents relating to purification methods. This is in addition to treatment patents, patents on dosing regimens, and, often, patents relating to methods of administration. IPRs provide a mechanism to "thin the herd" of patents covering critical biologic products in order to streamline BPCIA-based district court litigation bringing greater certainty to biosimilar development.[25]

Importantly, the IPR procedure has allowed biosimilar competitors a chance to invalidate wrongfully granted biologics patents early, often before the FDA has even

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[22] Eric Sagonowsky, *Targeting a $5B brand, Samsung and Merck launch Remicade biosim at 35% discount*, FiercePharma (July 24, 2017), https://goo.gl/YBKsdG.

[23] Michael T. Siekman & Oona M. Johnstone, *Impact of Post-Grant Proceedings on Biologics and Biosimilars*, BioProcess Int'l (Jan. 19, 2017), https://goo.gl/iNd78o.

[24] *See* Shayna B. Kravetz & Rosemary Frei, *Patent Reform Proposals Raise the Stakes for Researchers, Manufacturers of Biologics*, 1(2) Am. Health & Drug Benefits 13, 15 (Mar. 2008).

[25] *See* Siekman & Johnstone, *supra* note 23.

approved their biosimilar application. The advantage of this early invalidation is savings in cost and time. Through IPR, biosimilar companies can eliminate invalid patents before finalizing their biosimilar, giving them a chance to get to the market (and to patients) earlier than with the BPCIA procedures. Biosimilar manufacturers have found that

> IPRs provide a number of distinct advantages over litigating biologics cases in district court, including lower cost, lower burden of proof, and faster time to final judgment, as well as the enhanced technical expertise of the administrative patent judges. And for biosimilar applicants in particular, the relative simplicity and speed of IPRs can be an attractive means to avoiding the complexity of litigation under the Biologics Price Competition and Innovation Act, including the high volume of patents often in play and the corresponding two waves of litigation provided for by the act.

John Molenda & Richard Praseuth, *Current Trends In Biologics-Related Inter Partes Reviews*, Law360 (July 20, 2017), https://www.law360.com/articles/942459/current-trends-in-biologics-related-inter-partes-reviews (citations omitted). These advantages are precisely what Congress intended in passing the AIA and creating a biosimilar provision under the BPCIA.

D. Medical Device Companies Use the IPR Process to Cancel Invalid Patents.

Medical benefits through IPR challenges are not limited to the fields of biotechnology and chemistry but are also accessible to companies looking to clear the field of invalid patents covering medical devices. The U.S. medical device market is the largest medical device market in the world, with a market size around $140 billion in 2015.[26] While analysis of the cost and benefits of IPR challenges to medical devices is difficult, because prices are not often public, a similar correlation to generic drugs is plausible. One way to cut the costs of medical devices and, thus, the ultimate costs to the public is through increased competition.[27] IPR challenges have already invalidated medical device patents affecting a wide range of fields from the highly technical (e.g., tissue allografts used in reconstructive surgery[28] and heart valve implants[29]) to the less technical and more functional devices (e.g., eye-glass holders[30] and sleep therapy devices[31]). IPR

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[26] *See* Int'l Trade Admin., *Medical Technology Spotlight* (providing an overview of the medical technology industry in the U.S.), https://www.selectusa.gov/medical-technology-industry-united-states.

[27] Lars G. Svensson, *Aortic valve replacement: Options, Improvements, and Costs*, 80(4) Cleveland Clinic J. of Medicine (Apr. 2013).

[28] *See Tissue Transplant Technology, Ltd. v. MiMedx Group*, No. IPR2015-00420 (P.T.A.B. July 7, 2016).

[29] *See Medtronic, Inc. v. Norred*, Nos. IPR2014-00110 (P.T.A.B. Apr. 23, 2015); IPR2014-00395 (P.T.A.B. June 25, 2015).

[30] *See Chums, Inc. v. Cablz, Inc.*, No. IPR2014-01240 (P.T.A.B. Feb. 8, 2016).

challenges have opened the field for a broad range of medical devices such as endoscopy devices, surgical stapler devices, dental instruments and methods.[32]

One IPR decision currently on appeal to the Federal Circuit could open the field for hip implants, a highly active area of medical devices.[33] The patent partially invalidated by the PTO covers a porous hip implant said to optimize bone growth. It is estimated that as of 2010 about 2.5 million individuals in the United States have had a total hip replacement procedure.[34] A substantial number, around 2.3 million, of those with hip replacements are over the age of 50.[35] An affirmance by the Federal Circuit will allow the petitioner, medical device company Zimmer Biomet, as well as others, to further permeate the hip replacement market, bringing competition and likely a lower cost to the public.

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31 *See BMC Medical Co. LTD. v. ResMed Limited*, Nos. IPR2014-01196 (P.T.A.B. Jan. 19, 2016); IPR2014-01363 (P.T.A.B. Jan. 20, 2016).

32 *See Karl Storz Endoscopy-America, Inc. v. Novadaq Technologies, Inc.*, No. IPR2015-01847 (P.T.A.B. Mar. 8, 2017) (endocscopy devices); *Covidien LP v. Ethicon Endo-Surgery, Inc.*, No. IPR2013-00209 (P.T.A.B. Jun. 9, 2014) (surgical stapler devices); *See Cardiocom, LLC v. Robert Bosch Healthcare Systems, Inc.*, No. IPR2013-00431 (P.T.A.B. Jan. 15, 2015) (dental instruments and methods).

33 *See Zimmer Biomet Holdings, Inc. v. Four Mile Bay, LLC*, IPR2016-00012 (P.T.A.B. Mar. 10, 2017).

34 *See* Hilal Maradit Kremers, et al., *Prevalence of Total Hip and Knee Replacement in the United States*, 97(17) J. Bone Joint Surg. Am. 1386-97 (Sept. 2015).

35 *See id.*

Another IPR decision has led to increased competition in heart valve devices. In May 2016, the Federal Circuit affirmed the PTAB's determination that various claims of a patent directed to a replacement device for the aortic heart valve were invalid as obvious. *Norred v. Medtronic, Inc.*, 640 Fed. Appx. 994 (Fed. Cir. 2016) (affirming the results of IPR2014-00110 and IPR2014-00111 and dismissing as moot the result of IPR2014-00395). Heart disease remains the leading cause of death in the United States.[36] Heart valves alone can cost more than $32,000.[37] Since even Medicare recipients pay a share of cost, these costs can put a strain on individuals, as well as on insurance companies and taxpayers, who ultimately fund the balance of Medicare and Medicaid costs.

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[36] *See* CDC, Nat'l Ctr. for Health Stats., *Number of Deaths for Leading Causes of Death*, (providing an overview of the leading causes of death in the U.S.), https://goo.gl/jkVxKE.

[37] *See* Matthew R. Reynolds, et al., *Cost-Effectiveness of Transcatheter Aortic Valve Replacement With a Self-Expanding Prosthesis Versus Surgical Aortic Valve Replacement*, 67(1) J. of Am. Coll. of Cardiology 29-38 (Jan. 2016), *available at* http://www.onlinejacc.org/content/67/1/29; *see also* Svennson, *supra* note 27 .

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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October 30, 2017